

## REMARKS

This response is submitted in reply to the Final Office Action mailed March 27, 2008 ("the Action"). Applicant hereby requests further consideration of the application in view of the comments that follow.

The Action alleges that Mayhorn teaches a flat strip with a flat upper face and lower face (citing features 18, 20 and Figures 1, 2) and that the strap 18, 20 and pad 28 are made of flexible material. The Action thus alleges that one of skill in the art can "clearly envisage" that the flexible strip of Mayhorn terminates against flesh residing outside the labia minora and inside the labia major and that the flat upper face of the strip conforms to the shape of the wearer and defines a fluid-tight fit between the upper face of the strip and the flesh surrounding the labia minora and around the base of the labia minora. The Action opines that the anatomical features are "specific and different for each female" such that the flexibility of the materials used in Mayhorn makes the device fully capable of being adjusted according to the individual features of the wearer. Action, p. 3. Applicant respectfully disagrees.

First, Applicant submits that the anatomical features are not specific and different for each female. The size may vary but the anatomical features are largely the same. The device of Mayhorn fails to teach or suggest the configuration of the instant invention. Mayham's device is clearly designed to fit on an exterior of the vulva region which is bulky and does not provide the advantages of the instant invention. Mayhorn states that it is an object of his invention to "readily conform to and seal against the exterior of the vulva region." (col. 1, lines 41-44, emphasis added).

In contrast, the devices contemplated by embodiments of the invention employ a strip that contacts the wearer (there is no relatively bulky foamed plastic pad that resides on the strip to form the seal with the wearer). In further contrast, the instant invention is configured so that the labia minora can be pulled through the strip opening and the strip resides at a very different location from the sheet or pad of Mayhorn. That is, the labia majora is free -- allowing for more stability of the device as a wearer moves around as well as providing improved comfort and less bulk under garments.

Further, and notably, the Mayhorn device clearly resides on the outside of the vulva region and contacts the legs of the wearer. Indeed, the device clearly includes indentations 32, 34 on the outer perimeter of both the sheet 20 and the foamed plastic pad 28 that evidences this configuration. It is also clear that the foamed plastic pad 28 is not flat, but projects upwardly and varies in thickness from end to end from  $\frac{1}{4}$  inch thick to 1 inch thick (col. 2, lines 30-36). In contrast, *see* Claim 1. The independent claims are recited below for ease of discussion.

1. A non-intrusive female urinary incontinence device (13) comprising a flexible elastic substantially flat strip (1) having a flat upper face and a lower face, an opening (3) being provided in the strip communicating between the upper and lower faces, a fluid collection means surrounding (4) the opening in a fluid tight manner on the lower face of the strip and means (19) for attaching the device to a supporting means (17), wherein the strip and opening are sized and shaped such that when it is stretch fitted over the external urogenital organs, the labia minora extends through the opening and the strip terminates against flesh residing outside the labia minora and inside the labia majora and wherein the flat upper face of the strip conforms to the shape of the wearer and defines a fluid tight fit between the upper face of the strip and the flesh surrounding the labia minora and around the base of the labia minora, such that, in use, urine is conveyed from the urethra, through the labia minora, into the collection means without leakage.

17. A female urinary incontinence device, comprising:  
a strip having two opposing outer perimeter segments surrounding a urine flow passage, the outer perimeter segments sized and configured to reside snugly against flesh at a base region of a wearer's labia minora and within inner tissue folds of the wearer's labia majora so that the strip and flesh surrounding the base of the labia minora define a fluid-tight seal while allowing the labia minora to extend through the urine flow passage of the strip;

    a collection funnel sealably attached to the strip and in fluid communication with the urine flow passage of the strip; and

    a securing member configured to hold the strip in position on the wearer,

    wherein, in use, urine flows from the urethra, between the labia minora, then to the funnel in a leak-proof manner.

Attorney Docket No. 9052-250  
Application Serial No. 10/594,914  
Filed: September 29, 2006  
Page 4

19. A female fluid collection device, comprising:

a strip having two opposing outer perimeter segments surrounding a flow passage, the outer perimeter segments sized and configured to reside snugly against tissue surrounding a base region of a wearer's labia minora but within inner tissue folds of the wearer's labia majora so that the strip and tissue surrounding the base of the labia minora define a fluid-tight seal with the labia minora extending through the flow passage of the strip;

a collection funnel sealably attached to the strip and in fluid communication with the flow passage of the flat elastic strip; and

a securing member configured to hold the strip in position on the wearer,

wherein, in use, fluid flows from the body between the labia minora, then to the funnel in a leak-proof manner.

Applicant respectfully submits that Mayhorn fails to teach or suggest the emphasized features and indeed teaches away from the claimed invention. Applicant also respectfully submits that the Action fails to establish a *prima facie* case for rejections as the cited art fails to teach or suggest at least the emphasized features.

Attorney Docket No. 9052-250  
Application Serial No. 10/594,914  
Filed: September 29, 2006  
Page 5

### CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, she is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,



Julie H. Richardson  
Registration No.: 40,142

**USPTO Customer No. 20792**  
Myers Bigel Sibley & Sajovec  
Post Office Box 37428  
Raleigh, North Carolina 27627  
Telephone: 919/854-1400  
Facsimile: 919/854-1401

### CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on May 27, 2008.

Signature:



Cara L. Rose